

Regulatory Standards Division AMA-200

Document # WI 214.02

Revision

Title:

Product Development Planning Work Instruction

Page 1 of 4

REVISION HISTORY					
Rev	Description of Change	Author	Effective Date		
Α	Original	JLA	06/03/2003		
1	Update Form and Document Numbers	JLA	01/21/04		

REFERENCE DOCUMENTS				
Document Number	Document Title			
<u>QMS 200</u>	AMA-200 Quality Systems Manual			
QP 214	Product Development Procedure			

Documents referenced in this work instruction are applicable to the extent specified herein.

1. Purpose

This work instruction describes the development of a draft plan for the design and deployment of a customer requested project.

2. Scope

This work instruction applies to the planning stage of the Product Realization Procedure.

3. Definitions and Acronyms

See the QMS 200 and QP 214

4. Flowchart

There is no flowchart required for this document.

5. Responsibilities

5.1 The **Project Coordinator** (PC) shall:

- 5.1.1 Coordinate with the appropriate AMA-200 personnel, product lines and the customer.
- 5.1.2 Develop the Draft Plan.
- 5.1.3 Communicate plan development status.
- 5.1.4 Incorporate all approved changes to the Plan.
- 5.2 Project team members shall assist the Project Coordinator.



Title:

Regulatory Standards Division AMA-200

Document #

Revision

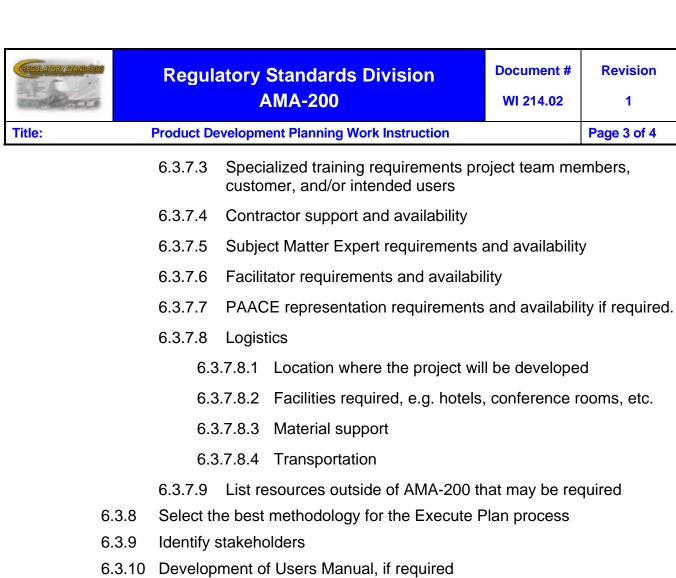
WI 214.02

Product Development Planning Work Instruction

Page 2 of 4

6. Work Instructions

- 6.1 The PC should develop the draft plan in coordination with the project team members.
- 6.2 Review the following documents:
 - 6.2.1 Customer Request Document
 - 6.2.2 Evaluation of Customer Request
 - 6.2.3 Project Overview Statement
 - 6.2.4 Previous planning if this is a resubmitted customer request
- 6.3 The following items should be considered in the development of the draft plan:
 - 6.3.1 A detailed statement of the customer request
 - 6.3.1.1 The statement should include the scope, purpose, and outcome of the project
 - 6.3.2 A time line for the project including the projected delivery date
 - 6.3.3 Develop a schedule of events that reflects project milestones, goals, objectives and deliverables.
 - 6.3.4 Status reporting requirements
 - 6.3.5 Communication Plan
 - 6.3.5.1 Internal, within AMA-200
 - 6.3.5.2 With the customer via the POC, relating to:
 - 1. Product information
 - 2. Questions, agreements, and when applicable, amendments
 - 3. Customer feedback, including complaints
 - 6.3.5.3 Collection and distribution structure
 - 6.3.5.4 Types of information to be disseminated
 - 6.3.6 Changes to the plan
 - See Plan Change Request Work Instructions (WI 214.04).
 - 6.3.7 Resources
 - 6.3.7.1 Automation requirements and compatibility
 - 6.3.7.2 Administrative support



- 6.3.9 Identify stakeholders
 6.3.10 Development of Users Manual, if required
 6.3.11 Coordination for access to applicable documents and standards, if required
- 6.3.12 Requirements for interface with current infrastructure or existing projects, if needed
- 6.3.13 State the scope of the verification process
 - 6.3.13.1 Identify a verification process that ensures the product meets the specific requirements in the Plan.
 - 6.3.13.2 Resource requirements for verification
- 6.3.14 State the scope of the validation process
 - 6.3.14.1 Identify a validation process that ensures the Product is capable of meeting the requirements for the specified application or intended use.
 - 6.3.14.2 Identify the resource requirements for validation
- 6.3.15 Post delivery requirements
- 6.3.16 Implementation guidelines (who and how?)



- 6.4 After the draft plan is complete, it will be forwarded through the Assigned Branch Manager to the Leadership Team for approval.
- 6.5 If the Leadership Team does not approve the draft plan, it is returned to the PC for correction.
 - 6.5.1 After correction the draft plan is resubmitted to the Leadership Team for approval.
- 6.6 If the draft plan is approved by the Leadership Team, it is forwarded to the PC to initiate the Execute Plan process.

7. Metrics

There are no metrics required for this document.

8. Quality Records

Quality Records for this document are listed in the table below. These records shall be generated and managed in accordance with AMA-200 Quality Records procedures.

Verifying Document Type or Number	Title	Retention Time
QF 210	Document Change Request (DCR)	Five Years

Quality forms are found in Appendix 1 of the AMA-200 QMS.